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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,743	01/23/2004	Robert L. Diaz	2385.005	6554
21917	7590	02/07/2006	EXAMINER	
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			HOFFMAN, MARY C	
			ART UNIT	PAPER NUMBER
			3733	
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Please find below and/or attached an Office communication concerning this application or proceeding.

SR

Office Action Summary	Application No. 10/769,743	Applicant(s) DIAZ, ROBERT L.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) 1-18 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/02/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a cutting guide, classified in class 606, subclass 86.
- II. Claim 4, drawn to a distractor, classified in class 606, subclass 90.
- III. Claims 5-8, drawn to a cutting block, classified in class 606, subclass 87.
- IV. Claims 9-16, drawn to an implant, classified in class 623, subclass 17.11.
- V. Claims 17-20, drawn to a kit, classified in class 606, subclass 102.
- VI. Claims 21-23, drawn to a method, classified in class 623, subclass 17.16.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention distractor has separate utility such as being used in a surgical operation which does not utilize a guide. See MPEP § 806.05(d).

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as functioning as a distractor to separate the vertebrae. See MPEP § 806.05(d).

Inventions I and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are

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shown to be separately usable. In the instant case, invention IV has separate utility such as placing an implant into the vertebrae does not require a cutting guide or any other type of sizing device. See MPEP § 806.05(d).

Inventions I and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require a planar forward end. The subcombination has separate utility such as being used with an implant other than an implant for an artificial spinal disk replacement.

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as distracting another body joint, such as the knee. See MPEP § 806.05(d).

Inventions II and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II has separate utility such as distracting another body joint, such as the knee. See MPEP § 806.05(d).

Inventions II and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and

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(2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require a frame. The subcombination has separate utility such as being used with an implant other than an implant for an artificial spinal disk replacement, such as an implant for the knee joint.

Inventions III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III has separate utility such as being used in a surgical operation of another body joint, such as the knee. See MPEP § 806.05(d).

Inventions III and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require a flange. The subcombination has separate utility such as being used with a type of implant other than an implant for an artificial spinal disk replacement, such as an implant for the knee joint.

Inventions IV and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP §

806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require a superior body. The subcombination has separate utility such as being used implanted without the aid of a guide.

Inventions I - V, and Invention VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus' can be utilized in a different method, such as a method where the disk space is expanded past the natural disc space to facilitate insertion of the instruments and/or implant.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required for the groups are different, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. FIG. 6-7
- B. FIG. 8-9
- C. FIG. 10

D. FIG. 11

E. FIG. 12-13

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims appear to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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During a telephone conversation with Michael Slavin on January 31, 2006 a provisional election was made with traverse to prosecute the invention of V, species D, claim 19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-18 and 20-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The abstract of the disclosure is objected to because it contains phrases that can be implied, i.e. "the present invention provides" and "the invention provides". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The

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disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: ref. #80'. Furthermore, ref. #89 in the written description is denoted as ref. #89' in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are informal and the reference numbers are difficult to read. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al. (U.S. Patent 6,949,105).

Bryan et al. discloses a surgical kit for disk arthroplasty comprising instruments and an artificial implant, the instruments being a sizing instrument (FIG. 4, ref. #18), a distractor (FIG. 19, ref. #140), and a cutting block (FIG. 32B, ref. #300) and an artificial implant having a mobile bearing (col. 61, lines 55-end, and col. 62, lines 1-9).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Bryan et al. (U.S. Patent Application 2003/0135277).

Bryan et al. disclose a surgical kit for disk arthroplasty comprising instruments and an artificial implant, the instruments being a sizing instrument (FIG. 19B, ref. #142), a distractor (FIG. 27, ref. #320), and a cutting block (FIG. 37, ref. #390) and an artificial implant having a mobile bearing (page 2, paragraph [0014]).

Claim 19 is rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (U.S. Patent Application 2004/0073311).

Ferree discloses a surgical kit for disk arthroplasty comprising instruments and an artificial implant, the instruments being a sizing instrument (page 4, paragraph [0076]), a distractor (page 4, paragraph [0078]), and a cutting block (page 4, paragraph [0080]) and an artificial implant having a mobile bearing (FIG.13).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER